

REMARKS

This application is a national stage application of PCT/US2005/004678. Pursuant to the OG Notice entitled "Revised Procedure for Preliminary Amendments Presented on Filing of a Patent Application," Nov. 8, 2005, the present application has been revised to include a Statement of Government Support (paragraph 002), as well as a new claim set (pages 63-66). No prohibited new matter has been added. Support for the new claims may be found throughout the specification of the PCT application as filed. Exemplary support for the new claims is indicated in the table below.

Claim	Support in Specification ¹
49. A composition suitable for inducing an immune response to anthrax in a subject when administered to a mucosal surface of the subject,	Original claim 32 Paragraphs 007, 035, 038, 081, 084
comprising two or more different isolated anthrax antigens	Paragraphs 009, 044, 047
and at least one mucosal adjuvant	Paragraphs 010, 086
in amounts suitable for inducing an immune response to anthrax in the subject, wherein the immune response can ameliorate or prevent at least one symptom of anthrax disease.	Original claim 16 Paragraphs 007, 037
50. The composition of claim 49, wherein the	Original claim 34

¹ Paragraph numbering refers to numbers used in the national stage application, which differs from the PCT application because of addition of paragraph adding Statement of Government Support

two or more different anthrax antigens are selected from the group consisting of non-vegetative anthrax spore antigens and vegetative anthrax bacterial antigens.	Paragraphs 039, 044, 083
51. The composition of claim 50, wherein the two or more different anthrax antigens are vegetative anthrax bacterial antigens selected from the group consisting of cell wall antigens, capsule antigens and secreted antigens.	Paragraph 044
52. The composition of claim 49, wherein the two or more different anthrax antigens are anthrax peptides selected from the group consisting of protective antigen (PA), lethal factor (LF), edema factor (EF), γ -D-glutamic acid (PGA), BclA and immunogenic fragments thereof.	Original claim 33 Paragraph 009, 011, 037, 046, 047
53. The composition of claim 52, wherein one of the two or more anthrax peptides is PA or an immunogenic fragment thereof and one is PGA or an immunogenic fragment thereof.	Original claim 38 Paragraph 047, Examples 4-6
54. The composition of claim 53, wherein at least some of the PA peptide is conjugated to the PGA peptide.	Original claim 39 Paragraphs 085 and 0148, Examples 4-6
55. (New) The composition of claim 54, wherein the PGA peptide is synthetic.	Paragraph 047

56. (New) The composition of claim 55, wherein the PGA peptide is a 10mer of poly(γ -D-glutamic acid).	Paragraph 024, Examples 4-6
57. The composition of claim 49, wherein the at least one mucosal adjuvant is selected from the group consisting of monophosphoryl lipid A (MPL), trehalose dicorynomycolate (TDM), signaling transducer receptor of LPS, chitosan and other positively charged polysaccharides and agonists of toll-like receptors.	Original claim 40 Paragraphs 010, 086, Example 5
58. The composition of claim 57, wherein the composition comprises two or more mucosal adjuvants.	Paragraph 086
59. The composition of claim 58, wherein one of the two or more adjuvants is chitosan and one is MPL.	Original claims 41-43 Example 5
60. The composition of claim 49, wherein the composition is formulated as a dry powder.	Paragraphs 098, 0148
61. The dry powder composition of claim 60 in combination with one or more devices for administering one or more doses of said composition.	Paragraphs 097, 0148

62. The dry powder composition of claim 61, wherein said one or more doses are unit doses.	Paragraph 097
63. The dry powder composition of claim 61, wherein the unit-dose container is a single-use nasal administration device.	Paragraph 0148
64. The composition of claim 49, wherein the immune response comprises a primary immune response.	Paragraph 042
65. The composition of claim 49, wherein the immune response comprises a secondary immune response.	Paragraph 042
66. The composition of claim 49, wherein the immune response comprises eliciting antigen-specific serum IgG.	Paragraph 042, Example 5, Tables 13 and 15
67. The composition of claim 49, wherein the immune response comprises eliciting antigen-specific secretory IgA.	Paragraph 040, Table 15
68. A method of inducing an immune response to anthrax in a subject, comprising administering to a mucosal surface of the subject an effective amount of the composition of claim 49.	Original claim 1 Paragraphs 007, 011, 037, 080, 084
69. The method of claim 68, wherein	Original claim 2

replication of anthrax in the subject is inhibited.	Example 5, paragraph 0153
70. The method of claim 68, wherein anthrax exotoxin in the subject is neutralized.	Original claim 19 Paragraphs 039, 043, 044, 083
71. The method of claim 68, wherein the immune response is a protective immune response.	Original claim 46 Paragraph 043
72. The method of claim 68, wherein the mucosal surface is selected from the group consisting of a nasal mucosal surface and an oral mucosal surface.	Original claim 17 Paragraph 085
73. The method of claim 68, wherein the subject has not been exposed to anthrax.	Original claim 16 Paragraphs 007, 011, 037, 043, 080, 084
74. The method of claim 66, wherein the subject is infected with anthrax.	Original claim 16 Paragraphs 007, 011, 037, 043, 080
75. The method of claim 68, wherein the subject has been exposed to anthrax.	Paragraph 0100
76. The method of claim 75, wherein the subject does not display visible signs of anorexia, lethargy and/or death as a result of exposure to anthrax.	Example 5, Table 15
77. The method of claim 76, wherein the	Example 5, Table 15

subject does not display visible signs of anorexia, lethargy and/or death up to 2 weeks after anthrax exposure.	
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Except for issue fees payable under 37 CFR §1.18, the commissioner is hereby authorized by this paper to charge any additional fees during the pendency of this application including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

If the Examiner has any further questions relating to this Amendment or to the application in general, he or she is respectfully requested to contact the undersigned by telephone so that allowance of the present application may be expedited.


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